Health Canada Santé Canada

Your health and safety... our priority. *Votre santé et votre sécurité... notre priorité.*

Registration Decision RD2010-12

Oxalic Acid Dihydrate

(publié aussi en français)

17 November 2010

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario
K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

HC Pub: 100517

ISBN: 978-1-100-16852-4 (978-1-100-16853-1)
Catalogue number: H113-25/2010-12E (H113-25/2010-12E-PDF)

© **Her Majesty the Queen in Right of Canada, represented by the Minister of Health Canada, 2010**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Registration Decision for Oxalic Acid Dihydrate

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, and Regulations, is granting full registration for the sale and use of Oxalic Acid Dihydrate Technical and Oxalic Acid Dihydrate, containing the technical grade active ingredient oxalic acid dihydrate to control Varroa mites in honeybee colonies.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1]: Proposed Registration Decision PRD2010-12 - *Oxalic Acid Dihydrate*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for oxalic acid dihydrate and summarizes the Agency's decision, the reasons for it and provides, in Appendix I, a summary of comments received during the consultation process as well as the PMRA's response to these comments. This decision is consistent with the proposed registration decision stated in PRD2010-12.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2010-12 - *Oxalic Acid Dihydrate* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

---

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

What Is Oxalic Acid Dihydrate?

Oxalic Acid Dihydrate is a dicarboxylic acid, which is a relatively strong organic acid. Oxalic Acid Dihydrate is used in honeybee colonies to control Varroa mites using two different application methods, as a solution by the trickle treatment method, and as a solid by the vaporisation method. Applications are made in the late fall to early spring, when little to no brood is present in the hive and honey supers are not in place.

While the mode of action of Oxalic Acid Dihydrate is not entirely understood, it appears to be mainly due to the low pH of the acid, which results in contact toxicity (physical injury of mites due to low pH). With the trickle-method of application, Oxalic Acid Dihydrate is dissolved into a 1:1 sugar:water solution, which is directly applied to the infested bees. The bees can tolerate the concentration of oxalic acid in the applied solution, but the Varroa mites cannot. With the vaporisation method of application, Oxalic Acid Dihydrate crystals are heated using a specialized application device until they liquefy and vaporise. Oxalic acid vapour fills the hive and all the bees and hive interior surfaces are covered with a very thin layer of Oxalic Acid Dihydrate crystals. While these fine crystals are tolerated by the bees, they are toxic to the Varroa mites.

Health Considerations

Can Approved Uses of Oxalic Acid Dihydrate Affect Human Health?

Oxalic Acid Dihydrate is unlikely to affect your health when used according to label directions.

Exposure to oxalic acid dihydrate may occur when handling and applying the end-use product, Oxalic Acid Dihydrate. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Since the technical grade active ingredient, oxalic acid dihydrate, is highly acutely toxic and corrosive to both the eye and skin, the statements, "DANGER – POISON", "DANGER – CORROSIVE TO EYES", and "DANGER – SKIN IRRITANT" have been included on the principal display panel of the general label and "Fatal or poisonous if swallowed", "DO NOT get in eyes", "CORROSIVE to the eyes", "DO NOT get on skin or clothing", "Corrosive to the skin", and "Avoid inhaling/breathing dust or fumes" have been included in the PRECAUTIONS section of the secondary display panel of the general label.

Residues in Water and Food

Dietary risks from food and water are not of concern.

It is anticipated that the amount of oxalic acid dihydrate present as a residue after application of the end-use product will not likely exceed the range of naturally occurring concentrations found in honey or vegetables. The direct application of oxalic acid dihydrate to beehives means that exposure to sources of drinking water will be negligible. Therefore, the use of oxalic acid dihydrate is not expected to result in dietary risk from food and/or water.

Occupational Risks From Handling Oxalic Acid Dihydrate

Occupational risks are not of concern when Oxalic Acid Dihydrate is used according to label directions, which include protective measures.

Pesticide applicators handling and applying Oxalic Acid Dihydrate to bee hives, can come in direct contact with oxalic acid dihydrate on the skin and in the eyes, as well as by accidental ingestion and inhalation. The current label statements adequately mitigate the concern of exposure to the applicators.

It is expected that only workers will be permitted access to the treated areas, thus the potential for bystander exposure is expected to be minimal and not of concern.

Environmental Considerations

What Happens When Oxalic Acid Dihydrate Is Introduced Into the Environment?

Oxalic acid is a naturally occurring compound that transforms rapidly under environmental conditions. Exposure of the chemical to the environment is expected to be limited during the use of Oxalic Acid Dihydrate for control of Varroa mite in beehives. The product is applied as a liquid or vapour to an affected colony; environmental exposure would occur primarily through spillage or leakage during application. Based on limited exposure, the chemical's natural occurrence and the likelihood for relatively rapid transformation under environmental conditions, the proposed use of Oxalic Acid Dihydrate is not expected to pose a significant risk to the environment. Therefore, further review of the environmental chemistry, fate, and toxicology of Oxalic Acid Dihydrate was not considered necessary.

Value Considerations

What Is the Value of Oxalic Acid Dihydrate?

Oxalic Acid Dihydrate has value for control of Varroa mite in honeybee colonies. Evaluated data demonstrated that Oxalic Acid Dihydrate can provide 90-99% control of Varroa mites in honeybee colonies when either the trickle treatment or vaporisation application methods are used when little to no honeybee brood is present in the hives (i.e. late fall to early spring).

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the labels of Oxalic Acid Dihydrate Technical and Oxalic Acid Dihydrate to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because there is a possibility of accidental oral, dermal, and inhalation exposure by workers, individuals should observe all precautionary and first aid statements on the product label. The label-required wearing of personal protective equipment by workers and the requirement to conduct activities in well ventilated areas are expected to minimize the potential for exposure to oxalic acid dihydrate. Based on the limited use pattern to bee hives, bystanders are not expected to be exposed to oxalic acid dihydrate.

Environment

No environmental risk-reduction measures are required. Standard label statements to protect the environment are required.

Other Information

1. The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

2. Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.inforserv@hc-sc.gc.ca).

[5]As per subsection 35(1) of the *Pest Control Products Act*.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

TGAI

PMRA #	Reference
966154	CHEMINFO. Oxalic Acid. www.intox.org/databank/documents/chemical/oxalicac/cie358.htm Retrieved: August 27, 2004. 13pp. Published, DACO: 2.14.1,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.3.1,2.4,2.5,2.6,2.7,2.8,3.1.4,3.5.1,3.5.10,3.5.11,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9,4.1,4.2.1,4.2.4,4.2.6,4.4.2,4.4.3,4.6 CBI
966156	Hazardous Substances Databank: Oxalic Acid. www.ccohs.ca. Retrieved June 28, 2004. 23pp. Published, DACO: 2.14.10,2.14.11,2.14.13,2.14.14,2.3.1,4.4.1,8.1,8.2.1,8.2.2.1,8.4.1,9.1 CBI
966159	Reregistration Eligibility Document. www.epa.gov/oppsrrd1/REDs/old_reds/oxalic_acid.pdf Retrieved June 28, 2004. Environmental Protection Agency, United States of America. 58pp Published, DACO: 12.5.4,12.5.8,12.7,2.11.1,2.11.2,2.11.3,3.2.1,4.1,4.2.1,4.2.3,4.3.2,4.3.5,4.4.1,4.5.1,4.5.2,4.5.9,4.6.3,4.7,7.2.4,8.1 CBI
1263986	Process for the Preparation of Oxalic Acid and Sodium Hydrogen Oxalate from Crude Sodium Oxalate. Canadian Patent 1314905, DACO: 2.11.1,2.11.2,2.11.3 CBI
1263987	Certificate of Analysis. www.univarcanada.com Retrieved June 20, 2004. 1p., DACO: 2.11.4,2.12.1,2.13.3 CBI
1263988	Specification Sheet. www.univarcanada.com Retrieved June 20, 2004. 1p., DACO: 2.12.2,2.15 CBI
1263989	2001, Sodium Hydroxide Titrations: Standard Operating Procedure, Quality Control. Sigma Aldrich, Sheboygan Canada, DACO: 2.13.1,2.13.2 CBI
1263990	2000, Nicolet Avatar ESP ESP FT-IR Sample Analysis, Quality Control. Sigma Aldrich, Sheboygan Canada, DACO: 2.13.2 CBI
1263991	2002, Melting Point Apparatus (Thomas Hoover Unimelt), Quality Control. Sigma Aldrich, Sheboygan Canada, DACO: 2.13.2 CBI
1263992	Jeanette G. Grasselli, Atlas Of Spectral Data and Physical Constants for Organic Compounds. CRC Press. Clevland, USA. P. B716, DACO: 2.14.12,8.2.1 CBI
1622413	certificate of analysis, DACO: 2.13.3 CBI
1622414	certificate of analysis, DACO: 2.13.3 CBI
1622415	certificate of analysis, DACO: 2.13.3 CBI
1622416	certificate of analysis, DACO: 2.13.3 CBI
1622417	certificate of analysis, DACO: 2.13.3 CBI
1658807	2008, 5 Batch Data, DACO: 2.13.3

EP

PMRA #	Reference
966154	CHEMINFO. Oxalic Acid. www.intox.org/databank/documents/chemical/oxalicac/cie358.htm Retrieved: August 27, 2004. 13pp. Published, DACO: 2.14.1,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.3.1,2.4,2.5,2.6,2.7, 2.8,3.1.4,3.5.1,3.5.10,3.5.11,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9,4.1,4.2.1,4.2. 4,4.2.6,4.4.2,4.4.3,4.6 CBI
966159	Reregistration Eligibility Document. http://www.epa.gov/oppsrrd1/REDs/old_reds/oxalic_acid.pdf Retrieved June 28, 2004. Environmental Protection Agency, United States of America. 58pp. Published, DACO: 12.5.4,12.5.8,12.7,2.11.1,2.11.2,2.11.3,3.2.1,4.1,4.2.1,4.2.3,4.3.2,4.3.5,4.4.1,4.5.1, 4.5.2,4.5.9,4.6.3,4.7,7.2.4,8.1 CBI
966029	Process For The Preparation Of Oxalic Acid And Sodium Hydrogen Oxalate From Crude Sodium Oxalate. Canadian Patents Database. Patent No CA 1314905. Published, DACO: 3.2.2 CBI
966030	Certificate of Analysis. www.univarcanada.com Retrieved Nov 20,2004. 1p. Not Published, DACO: 3.2.3,3.5.4 CBI
966031	Specification Sheet. www.univarcanada.com Retrieved Nov 20,2004. 1p. Not Published, DACO: 3.3.2 CBI
966032	Sodium Hydroxide Titrations: Standard Operating Procedure, Quality Control. 3pp. Published, DACO: 3.4.1 CBI
966036	Storage of Oxalic Acid Sucrose Solution. 3pp. Published, DACO: 3.5.10,7.2.5,7.3
966025	Hazardous Substances Databank: Oxalic Acid. www.ccohs.ca. Retrieved June 28, 2004. 23pp. Published, DACO: 5.1,5.3

2.0 Human and Animal Health

PMRA #	Reference
966154	CHEMINFO. Oxalic Acid. www.intox.org/databank/documents/chemical/oxalicac/cie358.htm Retrieved: August 27, 2004. 13pp. Published, DACO: 2.14.1,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.3.1,2.4,2.5,2.6,2.7, 2.8,3.1.4,3.5.1,3.5.10,3.5.11,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9,4.1,4.2.1,4.2. 4,4.2.6,4.4.2,4.4.3,4.6 CBI
966156	Hazardous Substances Databank: Oxalic Acid. www.ccohs.ca. Retrieved June 28, 2004. 23pp. Published, DACO: 2.14.10,2.14.11,2.14.13,2.14.14,2.3.1,4.4.1,8.1,8.2.1,8.2.2.1,8.4.1,9.1 CBI
966159	Reregistration Eligibility Document. http://www.epa.gov/oppsrrd1/REDs/old_reds/oxalic_acid.pdf Retrieved June 28, 2004. Environmental Protection Agency, United States of America. 58pp. Published, DACO: 12.5.4,12.5.8,12.7,2.11.1,2.11.2,2.11.3,3.2.1,4.1,4.2.1,4.2.3,4.3.2,4.3.5,4.4.1,4.5.1, 4.5.2,4.5.9,4.6.3,4.7,7.2.4,8.1 CBI
966165	Oxalic acid residues in honey. Melliferae.V,Imkerei Fischermuhle, 72348 Rosenfeld,Germany. 2pp. Published, DACO: 4.1,7.4,7.4.1

966166 Determination of residues in honey after treatments with formic and oxalic acid under field conditions. Apidologie 33:399- 409. Published, DACO: 4.1,7.4

966167 Health-based Reassessment of Administrative Occupational Exposure Limits: Oxalic Acid. The Hague, Health Council of the Netherlands, Netherlands. 18pp. Published, DACO: 4.1,4.2.1,4.2.3,4.2.5,4.3.1,4.3.5,4.4.1,4.5.1,4.5.6,4.6.1,4.6.2,4.6.3,4.6.5,4.7.1

966168 Oxalic Acid Content of Selected Vegetables. In Agricultural Handbook No 8-11: Vegetables and Vegetable Products. USDA, United States of America. 2pp. Published, DACO: 4.1,4.4.2,4.4.3

966169 Nanetti, A. et al., 2003, Oxalic Acid Treatments for Varroa Control (Review), Apiacta 38:81-87, DACO: 12.5.8,12.7

966170 2001, New Zealand Ministry Agriculture and Forestry, Oxalic Acid Registration Submission for Varroa Control. NZMAF. Wellington NZ pp 21, DACO: 12.5.8

3.0 Environment

PMRA # **Reference**

966154 CHEMINFO: Oxalic Acid. www.intox.org/databank/documents/chemical/oxalicac/cie358.htm Retrieved: August 27, 2004. 13pp. Published, DACO: 2.14.1,2.14.2,2.14.3,2.14.4,2.14.5,2.14.6,2.14.7,2.14.8,2.14.9,2.3.1,2.4,2.5,2.6,2.7,2.8,3.1.4,3.5.1,3.5.10,3.5.11,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,3.5.8,3.5.9,4.1,4.2.1,4.2.4,4.2.6,4.4.2,4.4.3,4.6 CBI

4.0 Value

PMRA # **Reference**

966043 Evaluation de l acide oxalique et de l acide formique en traitement du Varroa destructor pendant la période estivale. Centre de recherche en sciences animales de Deschambault, Quebec. 29 pp. Published, DACO: 4.1,7.4.1,10.2.3.2

966056 Varroa control with oxalic acid: a new application. In Proceedings of European Working Group for Integrated Varroa Control, Bern, Switzerland, June 16, 2000. 6pp. Published, DACO: 5.2,10.2.3.1

966058 Oxalic acid treatment by trickling: field against Varroa destructor recommendations for use in Central Europe and under temperate conditions. Bee World 83(2):51- 60. Published, DACO: 10.2.3.1,10.2.3.3,12.7

966060 Drip treatment with oxalic acid: tests 1999/2000 and recommendations for use in central Europe. Swiss Bee Research Centre, Liebefeld, Switzerland. 10pp. Published, DACO: 10.2.3.1,10.2.3.3

966061 Alternative Strategy in Central Europe for the Control of Varroa destructor in honeybee colonies. Apiacta 38:258-285. Published, DACO: 10.2.3.1,10.2.3.3

966062 Acaricidal effect of oxalic acid in honeybee(Apis mellifera) colonies. Apidologie 32: 333 340. Published, DACO: 10.2.3.3

966063 Efficacy and tolerability of an oxalic acid trickling treatment. In Proceedings of European Working Group for Integrated Varroa Control, Bern, Switzerland, June 16, 2000. 2pp Published, DACO: 10.2.3.3

966064 Vaporization of oxalic acid in a field trial with 1509 colonies. Presentation to European Working Group for Integrated Varroa Control, York UK June 2001.9pp, DACO: 10.3.2

966067 Oxalic Acid in Varroa Control. An overview of the last five years of experiments. Istituto Nazionale di Apicoltura. Bologna, Italy. 5pp. Published, DACO: 10.2.3.1,10.2.3.3

966070 Oxalic Acid Efficacy Against Varroa Mites in the Fall. 2002 and 2003. Ontario Tech Transfer Program, OBA. Guelph, Ontario, 7 pp. Published, DACO: 5.2,10.2.3.1,10.2.3.3

966072 Late Fall Efficacy of Oxalic Acid on Varroa Mites in Honeybee Colonies. 2001 and 2002 Trials. Ontario Tech Transfer Program, OBA, Guelph Ontario 4 pp. unpublished, DACO: 5.2,10.2.3.1,10.2.3.3

966074 Efficacy of Three Miticides (Oxalic acid, Formic acid. Apilife Var) on Varroa destructor and Acarapsis woodi in Honeybee Colonies in Canada. 8th European Meeting on integrated Varroa Control, Kirchain Germany-22-23May 2003, DACO: 5.2,10.2.3.1

966469 Efficacy of Three Miticides (Oxalic acid, Formic acid. Apilife Var) on Varroa destructor in Honeybee Colonies in Alberta. American Bee Journal. Submitted, DACO: 5.2,10.2.3.1,10.2.3.3

B. Additional Information Considered

i) Published Information

1.0 Human and Animal Health

PMRA #	Reference
1810547	C. Curtin et al., 1955, The Metabolism of Ascorbic Acid-1-C and Oxalic Acid-C In the Rat, DACO: 4.5.9
1810554	2004 TLVs and BEIs - Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices, DACO: 4.8
1810556	2003, The European Agency for the Evaluation of Medicinal Products, Committee for Veterinary Medicinal Products - Oxalic Acid Summary Report, DACO: 4.8
1810564	M. Grant, 1962, Toxicology of the Eye, DACO: 4.8
1810573	G. Hathaway et al., 1966, Chemical Hazards of the Workplace, DACO: 4.8
1810577	M. Goldman et al., 1977, Effect of Dietary Ingestion of Oxalic Acid on Growth and Reproduction in Male and Female Long-Evans Rats, DACO: 4.3.1
1810581	E.H. Vernot et al., 1977, Acute Toxicity and Skin Corrosion Data for Some Organic and Inorganic Compounds and Aqueous Solutions, DACO: 4.8
1810584	G. Clayton, 1982, Patty's Industrial Hygiene and Toxicology, DACO: 4.8

2.0 Value

Stanghellini and Raybold, Evaluation of selected biopesticides for the late fall control of Varroa mites in a northern temperate climate. American Bee Journal, 144:6, 2004, pp. 475-487.

Appendix I Comments

1. Two comments were received from beekeepers which supported the registration of oxalic acid dihydrate as a useful tool in managing Varroa mites in honeybee colonies.